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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,540	LI ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *21-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-20, drawn to an apparatus and method for making a physiological test and/or delivery of drugs, classified in class 600, subclass 584.

   II. Claims 21-44, drawn to a micro-laboratory for oral insertion, classified in class 600, subclass 582.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products and processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design, mode of operation, function, or effect. For example, invention I comprises a microchip, which performs a medical diagnoses or "physiological test"; the medical diagnosis may be an ultrasonic or laser scan of a tooth surface wherein the microchip would comprises an array of transducers to perform said functions. On the other hand, invention II comprises a microfluidic device for analyzing fluids or "collect oral fluids" wherein the fluid collection and/or analysis may be carried out through channels and/or biochemical reactions. Inventions I and II are thus distinct.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Daniel Dawes on November 10, 2005 a provisional election was made with traverse to prosecute the invention of group I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

5. Claims 8. 12. 14, 17, and 18-20 are objected to because of the following informalities:

In regards to claim 8, at line 1, "the cradle unit" should apparently read --a cradle unit-- to avoid a potential lack of antecedent basis problem.

In regards to claim 12, , at line 1, insert --wherein-- between "claim 9" and "collecting."

In regards to claim 14, at lines 2, "an integral units" should apparently read --an integral unit-- to avoid a potential indefiniteness problem.

In regards to claim 17, at line 2, "comprising" should apparently read --comprises--.

In regards to claim 18, at line 3, the adverb "as" renders the claim indefinite; it is unclear whether or not the limitations following the adverb are part of the claim.

In regards to claim 19:

at line 2, "comprise" should apparently read --comprises--;

at line 3, the adverb "as" renders the claim indefinite; it is unclear whether or not the limitations following the adverb are part of the claim;

at line 4, "based unit" should apparently read --base unit--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 4-5, 9, and 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuo (US Patent No. 6,623,698).

In regards to claim 1, Kuo discloses an apparatus for making a physiological test comprising:

an oral platform 6 ;

a microchip (i.e. matrix of sensors 138, 140) mounted on or in the platform for making medical diagnoses; and

a stick 32 connected to the platform 6 to serve as a handle on the platform 6 for exterior communication (see figs. 1a, 4a-c & 5a-c; column 6/lines 32-54 & 62-67; column 7/lines 1-20; column 8/lines 53-63; column 9/lines 32-50; column 10/lines 25-31; column 16/lines 40-51).

The Examiner notes that "a system" as hereinafter mentioned is intended to refer to either one of "an apparatus" or "a method."

In regards to claim 4, Kuo discloses an apparatus where the platform 6 has a plurality of fluidic ports (24, 26) defined therein conducive for communication of saliva to the microchip (see figs. 1c).

In regards to claim 5, Kuo discloses an apparatus further comprising a base unit 2 connected to the stick 32 and communicated to the microchip (see fig. 1).

In regards to claim 9, Kuo discloses a method for making a physiological test comprising:

providing an oral platform 6;

collecting saliva through the oral platform 6;

delivering collected saliva to a microchip (i.e. matrix of sensors 138, 140) mounted in the platform 6; and

making a medical diagnosis from collected samples of saliva through the platform 6 (see figs. 1a, 4a-c & 5a-c; column 6/lines 32-54 & 62-67; column 7/lines 1-20; column 8/lines 53-63; column 9/lines 32-50; column 10/lines 25-31; column 16/lines 40-51).

In regards to claim 12, Kuo discloses a method where collecting saliva through the oral platform 6 comprises collecting saliva through a plurality of fluidic ports (24, 26) defined therein and communicating the collected saliva to the microchip (see fig. 1c).

In regards to claim 13, Kuo discloses a method further comprising communicating the microchip with a base unit 2 (see figs. 2a-b).

8. Claims 1, 4, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Doneen et al. (US Patent No. 6,102,872).

In regards to claim 1, Doneen et al. discloses an apparatus for making a physiological test and/or delivery of drugs comprising:

an oral platform 10';

a microchip 30 mounted on the platform for making medical diagnoses; and

a stick 26 connected to the platform to serve as a handle on the platform for exterior communication (see figs. 1-3; column 2/lines 33-47; column 3/lines 44-56; column 5/lines 35-44; column 6/lines 17-21; column 7/lines 31-33 & 40-54).

In regards to claim 4, Doneen et al. discloses an apparatus where the platform has a plurality of fluidic ports 22 defined therein conducive for communication of saliva to the microchip 30 (see fig. 1; column 7/lines 31-33).

In regards to claim 9, Doneen et al. discloses a method for making a physiological test and/or delivery of drugs comprising:

providing an oral platform 10';

collecting saliva through the oral platform 10';

delivering collected saliva to a microchip 30 mounted on the platform 10'; and

making a medical diagnosis from collected samples of saliva through the platform 10' (see figs. 1-3; column 2/lines 33-47; column 3/lines 44-56; column 5/lines 35-44; column 6/lines 17-21; column 7/lines 31-33 & 40-54).

In regards to claim 12, Doneen et al. discloses a method where collecting saliva through the oral platform 10' comprises collecting saliva through a plurality of fluidic ports 22 defined therein and communicating the collected saliva to the microchip 30 (see fig. 1; column 7/lines 31-33).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 2, 6, 10, 14, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo ('698) in view of Feller et al. (US Patent No. 5,897,492).

The Examiner notes that "a system" as hereinafter mentioned is intended to refer to either one of "an apparatus" or "a method."

Kuo discloses a system, as described above, that teaches all the limitations of the claims except Kuo does not teach a candy shell coating. However, Feller et al.

discloses an apparatus 10 comprising a candy shell coating 12; wherein said apparatus is shaped like a lollipop (see fig. 1; column 2/lines 58-64).

Since Kuo teaches interchanging its oral device with other element used for dental or medical functions (see column 16/lines 40-51) and Feller et al. teaches an element used for dental functions, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo with a candy coating similar to that of Feller et al. in order to reduce the anxiety associated with oral examinations (see Feller et al., column 1/lines 44-53).

Moreover, since Kuo as modified by Feller et al. teaches interchanging its oral device with other element used for dental or medical functions (i.e. replacing the bristles with a candy shell) (see rejection supra), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Feller et al. with a plurality of base units which are interchangeable with a plurality of lollipops for making a plurality of medical diagnoses since such a modification would amount to a design choice. It has previously been held that duplicating part for a multiple effect is not patentable--See *In re Harza, 274 F.2d 669, 671, 124 USPQ 378, 380 (CCPA 1960).*

11. Claims 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo ('698) in view of Feller et al. ('492) further in view of Blankenship (US Patent No. 6,165,495).

Kuo as modified by Feller et al. discloses an apparatus, as described above, that teaches all the limitations of the claims except Kuo as modified by Feller et al. does not

teach providing medicinal agents in the candy shell. However, Blankenship discloses an apparatus comprising medicinal agents (see figs. 1-2; column 2/lines 55-63; column 3/lines 3-16).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Kuo as modified by Feller et al. with medicinal agents similar that of Blankenship in order to appeal to small children (see column 3/lines 3-5).

12. Claims 7-8 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo ('698) in view of Feller et al. ('492) further in view of Lundell et al. (US Patent No. 5,994,855).

Kuo as modified by Feller et al. discloses a system, as described above, that teaches all the limitations of the claims except Kuo as modified by Feller et al. does not teach coupling the system to a cradle unit. However, Lundell et al. disclose a system 10 comprising a cradle unit 28 capable of temporarily being coupled to a base unit 12 (see fig. 1).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Feller et al. with a cradle unit similar to that of Lundell et al. in order to recharge the battery as is well known in the art.

Moreover, in regards to claims 7 and 15, Kuo as modified by Feller et al. as further modified by Lundell et al. discloses an apparatus comprising a data processing communication (34, 35) and display 178 (see fig. 5h). As such, it would have been

obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Feller et al. as further modified by Lundell et al. with a cradle unit that provides data processing communication and/or display since such a modification would amount to a design choice. It has previously been held that shifting location of parts is not patentable--*See In re Japikse, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950).*

13. Claims 3, 11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo ('698) in view of Feller et al. ('492) further in view of Doneen et al. ('872).

Kuo as modified by Feller et al. discloses an apparatus, as described above, that teaches all the limitations of the claims except Kuo as modified by Feller et al. does not teach providing medicinal agents in the candy shell. However, Doneen et al. disclose an apparatus 24 comprising medicinal agents; wherein the medicinal agent comprise saliva producing agents (i.e. citric acid) (see column 2/lines 42-47; column 6/lines 17-21; column 7/lines 44/46).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Feller et al. with medicinal agents similar to that of Doneen et al. in order to stimulate saliva for testing (see Kuo, column 9/lines 11-12; see Doneen et al., column 2/lines 42-47; column 6/lines 17-21; column 7/lines 44/46).

Moreover, changing the type/method of salivary gland stimulation is a design choice (i.e. using a chemical stimulant over a brush). It has previously been held that

changing aesthetic design is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,150,178 to Cesarczyk et al. discloses a diagnostic testing device.

US Patent No. 6,248,598 to Bogema discloses an immunoassay that provides for both collection of saliva and visual readout.

US Patent No. 5,611,995 to De Zoeten et al. discloses an apparatus for the detection of a specifically reacting surface.

US Patent No. 5,609,160 to Bahl et al. discloses an in-home oral fluid sample collection device.

US Patent No. 6,440,087 to Sangha discloses an oral fluid collection device and method.

US Patent No. 6,241,689 to Chard et al. discloses a diagnostic test apparatus.

US Patent No. 6,303,081 to Mink et al. discloses a device for collection and assay of oral fluids.

US Patent No. 5,714,389 to Charlton et al. discloses a test device for colored particle immunoassay.

US Patent No. 6,537,525 to West discloses a medicated chewing-gum.

US Patent No. 6,641,543 to Osgoodby discloses a flavored thermometer.

US Patent No. 4,346,493 to Goudsmit discloses a dental-care device and brush suitable therefor.

US Patent No. 4,551,329 to Harris et al. discloses an oral medicament lollipop.

US Patent No. 3,142,852 to Phaneuf et al. discloses an automatic toothbrush.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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